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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,090	Applicant(s) HAREL, MOTI	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-122 is/are pending in the application.
- 4a) Of the above claim(s) 101, 102 and 117-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-100, 103-116, 121 and 122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/6/05, 1/5/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 87-122 are currently pending. Claims 87-100, 103-116, 121, and 122 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 117-120 are withdrawn from consideration.

Election/Restrictions

Applicants' election of Group I (claims 87-116, 121, and 122) in the reply filed on Oct. 27, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 101, 102, and 117-120 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Per the species election set forth in the restriction requirement dated Sep. 26, 2008, applicant has elected microbes as the species of bioactive agent. Claims 101 and 102 are not drawn to microbes, but rather to proteins and antibiotics. Thus, claims 101 and 102 are withdrawn from consideration as being drawn to a non-elected species.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Nov. 6, 2003, the filing date of PCT application PCT/US03/35250 to which the instant national stage 371 application claims priority.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. In order to receive the benefit of an earlier filing date under 35 U.S.C. 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of prior-filed provisional Application No. 60/424,324 (filed Nov. 7, 2002) fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for claims 87-100 and 103-116, of the instant application. Instant claim 87 recites a particle comprising alginate, a non-digestible polymer, and an emulsifier, wherein the alginate comprises from about 0.5 to about 2.0 % wet weight of the particle, and wherein the total amount of polymer comprises from about 0.1 to about 6 % wet weight of the particle. Regarding these limitations, the closest teaching in the provisional application is found in Example 11, Table 7, which discloses a particle comprising 2.0 wet weight % alginate, 4.0 wet weight % amylase (a

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non-digestible polymer), and egg lecithin (an emulsifier). However, this example does not adequately disclose the *ranges* of these components recited in claim 87. A particle comprising all of these components in the instantly claimed % ranges is not adequately disclosed or claimed in the above referenced provisional application. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith* 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05. Thus, claims 87-116 cannot be afforded the date of the provisional application and are afforded the date of the corresponding PCT application to which the instant national stage 371 application claims priority. Claims 121 and 122 are supported by Example 11 of the provisional application and are afforded a date of Nov. 7, 2002.

Claim Objections

Claim 95 is objected to because of the following informalities: the word "amylase" in line three of the claim should be "amylose".

Appropriate correction is required.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claim 95 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 95 recites "derivatives" of starch and cellulose.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106). See MPEP § 2163.

Applicant has failed to provide any further description of the various derivatives as recited in instant claim 95 that would provide adequate written description of the compounds encompassed by the claim. Adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties. Applicants provide no direction as to what subset of derivatives out of all possible derivatives that exist in the art would possess the required properties and be useful to

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form a controlled-release particle with alginate. The term "derivatives" is extremely broad and encompasses, for example, salt forms, reaction products, and degradation products. It is noted that in the present case, no examples of the claimed derivatives are provided or described. The skilled artisan would have been unable to readily envision the chemical structures of the claimed subject matter (i.e. the entire genus encompassed by the claim). Thus, the disclosure fails to describe the claimed compounds in a manner that complies with the written description requirement of 35 U.S.C. 112, 1st Paragraph.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 87-100 and 103-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 87-100 are indefinite in the recitation "...the total amount of the polymer comprises from about 0.1 to about 6 percent by wet weight of the particle..." in claim 87. It is noted that there are two polymers recited in claim 87 prior to this limitation. The first polymer recited is alginate (which is a polymeric material), while the second polymer recited is designated generically as a "non-digestible polymer". Due to the difference in nomenclature, it is unclear whether the "total amount of polymer" recited in claim 87 refers to both alginate and the non-digestible polymer or to only the non-digestible polymer. Use of the singular "polymer" in line 3 of the claim further confuses the issue.

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If the term "total polymer" was intended to refer to both alginate and the non-digestible polymer, why is this term not plural (i.e. polymers)? If this was the intended meaning of the limitation, the examiner suggests replacing the term "polymer" with "alginate and the non-digestible polymer" to make the meaning clear.

Furthermore, it is noted that the minimum percentage of alginate in the composition is 0.5% and the minimum percentage of the total polymer is less than this, 0.1%. These values would further lead the ordinary artisan to believe that the "total amount of polymer" refers to only the non-digestible polymer since even the minimum amount of alginate alone would exceed the minimum range of the "total amount of polymer", let alone if the alginate were in combination with the non-digestible polymer. However, this interpretation is inconsistent with the plain meaning of the limitation "...the total amount of polymer..." Therefore, as written, the ordinary artisan would not be apprised of the scope of the invention since the artisan could reasonably construe "the total amount of the polymer" to refer to both alginate and the non-digestible polymer or to only the non-digestible polymer. Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or guidance in the specification, the metes and bounds of these claims are indefinite.

Claim 87-100 and 103-116 recites a non-digestible polymer chosen from various species, including high amylose starch. It is noted that starch is digestible by humans. Even high amylose starch is digestible by humans, albeit at a much slower rate than typical starch or the amylopectin component of starch. It is also noted that cellulose (see claim 95) is digestible by termites. The term "digestible" has not been defined in

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the instant specification. Thus, it is not clear what standard is to be used to measure whether or not a particular polymer is non-digestible. Is the polymer not able to be digested only by humans? Or not digestible by any species of animal? Or not digestible by isolated enzymes or other chemical methods? Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or guidance in the specification, the metes and bounds of these claims are indefinite.

Claim 100 recites various genus of bacterial species (e.g. *Bacillus* spp., *Lactobacillus* spp.), which are followed by individual bacterial species within each genus. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Claim 100 recites the broad ranges (bacterial genus) and also recites more narrow ranges (bacterial species within each genus). Thus the claim is indefinite.

Claim 103 recites, "The composition of claim 87 wherein the composition is in a dry form." The composition recited in claim 87 necessarily includes water or some other liquid since the percentages are in terms of wet weights. It is unclear how the liquid-containing composition of claim 87 can be in a dry form. Thus, the claim is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 121 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by NAKATSUKA (U.S. Patent No. 4,076,846; Issued Feb. 28, 1978).

1. Nakatsuka discloses edible starch compositions for use in feedstuffs, agriculture, and fisheries (abstract). Nakatsuka discloses granules (i.e. particles) comprising alginate, high-amylose starch (i.e. a non-digestible polymer as set forth in the instant specification), and lecithin (i.e. an emulsifier) (column, 15, Table 4, Example 8), reading on claim 121. The particles described in Example 8 comprise casein (i.e. a protein), glycerol, and sorbitol, any one of which qualifies as a bioactive agent per the description of bioactive agents in the instant specification (paragraph [0039]). In addition to the category of proteins (of which casein is a member), suitable bioactive agents are stated to include drugs. Both glycerol and sorbitol have been used as laxatives, and thus may fall into the broad category of drugs. Thus, Nakatsuka anticipates claim 122.

Claims 121 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by LEE (U.S. Patent No. 5,362,424; Issued Nov. 8, 1994).

2. Lee discloses microcapsules comprising alginate, starch (i.e. a non-digestible polymer as set forth in the instant specification), bile salt (i.e. an emulsifier), and 5-fluorouracil (i.e. a drug), reading on claims 121 and 122.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 87-96, 98, 103, 104, 108-112, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over KÜRZINGER (U.S. Patent No. 6,303,175; Issued Oct. 16, 2001) in view of Nakatsuka.

3. As noted above under 112 2nd paragraph rejections, there are issues of indefiniteness with claims 87-96, 98, 103, 104, 108-112, and 114. Thus, for the purposes of the following rejections, the term "total amount of polymer" will be given its plain meaning and is interpreted to refer to both alginate and the non-digestible polymer. Furthermore, for the purposes of the following rejections, the term non-digestible has been interpreted to include only those polymers recited in claim 95. For the purposes of the following rejections, claim 103 will be interpreted as being dried after forming the composition of claim 87.

4. Kürzinger discloses particulate feeds for aquatic animals, especially fish, shrimps, and invertebrates (abstract; column 2, line 65; column 3, lines 19-25; claims 12 and 13). The preferred feed contains 0.001-50%, of a gel forming compound or compounds that may be alginate in combination with other polymers such as, *inter alia*, starches, cellulose materials, guar gum, or gum arabic (abstract; column 2, lines 17-26). 0.1-10% of the gel forming component(s) is especially preferred (abstract; column 1, line 67 to column 2, line 3; claims 1-5). Examples of the gel forming component(s) present in the range of 1.5-5.5% are provided (column 3, lines 50-58, Variant 1). These percentages are taught with respect to compositions comprising particular water contents (e.g. 50-99% or 73-94% water) (abstract; column 2, line 3; column 3, lines 50-58, Variant 1), and are thus wet weights. Kürzinger specifically teaches that the gel

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formers can be used alone or preferably in synergistic combinations, improving the acceptance and properties of the feed (column 2, lines 32-34). Kürzinger teaches the inclusion of emulsifiers such as lecithin for the improvement of consistency and binding of the feed mixture (column 2, lines 44-50). Kürzinger also teaches that the compositions can be treated by drying (column 3, lines 19-23).

5. Kürzinger does not specify a suitable weight ratio of emulsifier to the non-digestible polymer. The ordinary artisan would have looked to the literature for guidance regarding appropriate amounts of emulsifier to include in the composition.

6. Nakatsuka discloses edible particulate compositions for use in feedstuffs, agriculture, and fisheries (abstract). Nakatsuka discloses granules (i.e. particles) comprising alginate, high-amylose starch (i.e. a non-digestible polymer as set forth in the instant specification), and lecithin (i.e. an emulsifier) (column, 15, Table 4, Example 8). Nakatsuka teaches that lecithin is particularly suitable for use with starch materials because it has a desirable affinity toward starch and has an adequate hydrophilic-lipophilic balance (column 7, lines 59-63). Furthermore, Nakatsuka teaches that up to 10% by weight or more of lecithin can be added, as embodied in examples 7-9 and 20-23 (column 7, line 65 to column 8, line 6). Nakatsuka also teaches that a composition containing about 10% by weight lecithin has favorable release properties (column 7, lines 66-68). While it is noted that only 1 part by wet weight lecithin is exemplified in examples 7-9, the teaching of up to 10% lecithin is clear, and one of ordinary skill in the art would have recognized the advantages of the release properties in the feed production process as taught by Nakatsuka.

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7. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to utilize from 1% up to 10% wet weight lecithin, in the composition of Kürzinger to provide a particulate feed composition having favorable release properties per the teachings of Nakatsuka. One would have been motivated to do so since Nakatsuka teaches that lecithin is particularly suited to similar feed compositions comprising starch, and since Nakatsuka teaches that such amounts are advantageous. Further, one would have had a high expectation of success in doing so since Kürzinger teaches the use of both starch and lecithin in the feed compositions (column 2, lines 23 and 50; claim 3).

8. Based on the teachings of Kürzinger the ordinary artisan would have a high expectation of success in combining alginate and any of several non-digestible polymers. The artisan would be guided by Kürzinger's teaching of using a combination of these polymers wherein each could be present in amounts such that the total of the two polymeric components is between about 5.5% and 10% wet weight. Thus, the inclusion of lecithin at the levels taught by Nakatsuka would result in compositions wherein the emulsifier (i.e. lecithin) is present in a ratio of between about 1:2 relative to the non-digestible polymer. It is well within the skill of the ordinary artisan to optimize the precise amounts of these components, particularly given the relatively narrow teachings of Kürzinger and Nakatsuka. Furthermore, there is nothing of record to show the criticality of the claimed percentage ranges. Therefore, the combination of Kürzinger and Nakatsuka reads on claims 87-95, 103, and 104.

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9. As discussed above, under 102 rejections Nakatsuka teaches proteins and other components that qualify as bioactive agents based on the examples provided in the specification. It is noted that the terms "microstructure" and "nanostructure" have not been given special meaning in the specification. Thus, these terms have been interpreted broadly, and encompass the natural feed components disclosed by Kürzinger, such as zooplankton. Furthermore, zooplankton are microbes (i.e. microscopic organisms) (elected species), and are clearly bioactive agents as defined in claim 98. Thus, the combination of Kürzinger and Nakatsuka reads on claim 96 and 98. Both Kürzinger and Nakatsuka disclose compositions comprising glycerol (see column 2, lines 35-38 of Kürzinger), which is classified by the FDA as a caloric macronutrient, reading on claim 108.

10. While the feed taught by Kürzinger is intended for aquatic animals, the ordinary artisan would readily envisage the possibility of its administration to humans, particularly, in light of Nakatsuka's teaching that the components of the composition should have no harmful effect on the human body (column 7, lines 41-46). Since many of the species raised in aquaculture are intended for human consumption, the compositions must also be acceptable for human consumption as would be recognized by the ordinary artisan. Thus, the combination of Kürzinger and Nakatsuka renders claim 109 obvious.

11. As noted *supra*, the feed taught by Kürzinger is for aquatic animals, especially fish, shrimp, and invertebrates (abstract). Further Kürzinger teaches the use of the disclosed feed for ornamental fish in an aquarium (i.e. domestic animals). Since

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Nakatsuka teaches that the components of the composition should have no harmful effect on the human body, one of ordinary skill in the art would readily have envisioned humans as a target animal for the feeds of the invention, particularly since many of the aquaculture species for which these feeds are intended are raised for human consumption, either directly or indirectly. Thus, the combination of Kürzinger and Nakatsuka renders claims 110-112 and 114 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 87, 97-100, 103, 105-107, 113, 115, and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kürzinger in view of Nakatsuka as applied to claims 87-96, 98, 103, 104, 108-112, and 114 above, and further in view of VILLAMAR (WO 02/00035; published Jan. 3, 2002).

12. The teachings of Kürzinger and Nakatsuka have been presented *supra*. It is noted that applicant has defined "controlled release" delivery systems to include

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systems manipulated to assure that the materials within a particle are delivered intact to the desired location (paragraph [0046]). Based on this definition, the particles of Kürzinger also provide controlled release since they allow the materials within the particles (i.e. the natural feed components) to be delivered intact to the desired location, that being the stomach of the animal. - Additionally, Kürzinger teaches the use of a variety of natural feed components, but does not explicitly teach the inclusion of the microbes recited in claims 99-100. Kürzinger does not teach the particle sizes recited in claims 105 and 106 and does not teach bioattractants.

13. It is noted that alginate-containing beadlets and particles for aquaculture use are well known in the art and many are used as controlled release compositions. For example, Villamar discloses a bioactive food complex in the form of particles or microcapsules that comprise alginate and other non-digestible polymers as well as emulsifiers such as lecithin (page 10, 2nd and 3rd paragraphs; page 14, 3rd paragraph; page 16, 2nd paragraph). These feed particles serve to deliver different bioactive components to the digestive tract (such as the intestines) of animals such as shrimp or fish or other livestock raised commercially to control bacterial disease in such livestock (abstract, page 7, 2nd paragraph). Thus, the compositions of Villamar are controlled release compositions for the bioactive agent(s) incorporated therein. Villamar teaches the inclusion of probiotic bacteria in the compositions of the invention (abstract), and teaches that *Bacillus* sp., *Lactobacillus* sp., and other bacteria are probiotics commonly added to feeds in the animal agriculture industry (page 6, last paragraph).

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14. One of ordinary skill in the art would recognize that the animal agriculture industry includes such feedstock animals as mollusks, rotifers, and artemia. Furthermore, Villamar teaches adjusting the size and shape of the bioactive food complex to complement the feeding mechanism and behavior of the aquatic animal target species (page 17, 1st and 2nd paragraphs). In particular, Villamar teaches the production of particles in the size range of about 20-200 μm for small/larval animals and particles from about 100-1000 μm for larger/postlarval animals. Villamar also teaches the use of bioattractants (page 11, top paragraph).

15. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include known probiotic bacteria such as *Bacillus* spp. in the compositions of Kürzinger. One would have been motivated to do so since Villamar teaches that probiotic bacteria are advantageous for controlling bacterial disease in aquaculture. Based on Villamar's teachings, it also would have been *prima facie* obvious to adjust the particle size of the compositions (including particles of about 150 μm) and include a bioattractant as needed to feed any cultivated aquatic animal, as would be recognized by the ordinary artisan. Further, one would have had a high expectation of success in doing so since the compositions of Villamar comprise alginate, other non-digestible polymers, and lecithin as do those of Kürzinger. Thus, the combination of Kürzinger, Nakatsuka, and Villamar renders obvious claims 87, 97-100, 103, 105-107, 113, 115, and 116.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

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Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

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